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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,60-71 and 89-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60-71,89 and 90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continued Prosecution Application

The request filed on June 29, 2002 and November 12, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/392,842 is acceptable and a CPA has been established. An action on the CPA follows.

Prosecution on the elected bigunide polymer specie of poly(hexamethylenebiguanide), and water-insoluble organic compound specie of methylene-bis-N,N-diglycidylaniline, as set forth in Paper No. 8, is hereby continued. Claims 58, 60-71, 89-98 are pending.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 58, 60-71, 89-98 are rejected under 35 U.S.C. 102(a) as being anticipated by Sawan et al WO 98/18330 ('330).

The instant claims are directed to methods providing antimicrobial activity on skin comprising administering to skin a biguanide polymer, a metallic material, and a carrier, the biguanide polymer is poly(hexamethylenebiguanide) (PHMB) present as an adduct (crosslinked) with a substantially water-insoluble organic compound specie such as methylene-bis-N,N-diglycidylaniline (MBDGA), and an antimicrobial metal such as silver.

'330 patent discloses methods of preparing a solution of PHMB polymers crosslinked by MBDGA, coating an article with the solution, and then immersing the coated article in a silver iodide/potassium iodide alcohol solution and further be dissolve in a carrier and be used as a topical antiseptic, wound dressing or topical disinfectant (pages 16-18, 20 line 25-page 22, line10, 24-26, and example 17). '330 disclose that the coated article have higher antimicrobial activity after being coated, thus their anti-microbial activity is enhanced (example 4-6, claims 1-37). '033 repeatedly states that the composition can be administered to a subject in various ways including trough a wound dressing, a catheter, or a fiber material, thus, such modes of administration, meets the requirement of the instant claims which are directed to generically administering to akin a composition. Accordingly, '330 meet the limitations of the instant claims.

Claims 58, 60-64, 89-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown US Patent 4,643,181.

Brown discloses antimicrobial coating compositions comprising an antimicrobially effective amount of polycationic polymer such as PHMB. Brown discloses adjusting the

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biocidal activity of a hydrophobic acrylate-type adhesive and enhancing its activity against *S. aureus* (col 7 lines 25-55, claims 1-7). Brown further administers his composition through a dressing on the skin of volunteers (see col 8, lines 55-65). The Accordingly, Brown meets the limitations of the instant claims

Claims 58, 60-71, 89-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawan et al WO 95/17152 ('152).

'152 discloses antimicrobial coating compositions comprising PHMA-MBDGA-silver coating mixtures, and methods of using them to enhance antimicrobial activity of various articles or topical compositions such as eye care products (35-39, page 40, paragraph b-d, pages 46-49. Claims 1, 18-20, 29-53). '152 patent meets the limitations of the instant claims.

Claims 58, 60-71, 89-98 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawan et al US Patent 5,817,325.

Sawan et al disclose methods of enhancing devices and formulations comprising a PHMB-MBDGA-silver coating on a device or a dermal composition, (col 15-17). Thus, Sawan et al meet the limitations of the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 60-71, 89-98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker, and/or methods of using such compositions to improve the antimicrobial activity of an article or a secondary formulation.

For example, claims of the patent 6,018,584 are directed to methods of providing antimicrobial activity on skin by applying the claimed invented disinfectant composition on a substrate (claims 1, 27-33). The instant claims differ from the patented claims only by the nature of the substrate. However, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the compositions of the patented claims on suitable substrates including scrubs, skin preparations directly or through suitable carrier systems. Accordingly, the instant claims are obvious modification of the already patented claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 58, 60-71, 89-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown US Patent 4,643,181 in view of Sawan et al WO 95/17152 ('152).

The teachings of Brown are described above. Brown fails to link PHMB biguanide polymers to a water-insoluble organic compound to increase its activity.

Sawan '152 teaches that the cross-linking of PHMB with a water-insoluble organic compound such as MBDGA enhances the final activity.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to cross link PHMB of Brown with MBDGA of Sawan to enhance therapeutic effects of Sawan's antibacterial activity.

Request for Interview

Applicant's request for telephonic interview is noted. However, at this point Examiner feels that the limitations of the pending claims are clearly taught in the art. Nevertheless, upon request, Examiner tried to contact the attorney of record on January 23, 2002 but failed to establish communication. Subsequently, this Office Action is issued. If Applicant believes that a conversation with Examiner would be helpful in clarifying the issues in dispute, Applicant is invited to contact Examiner Sharareh.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss, January 25, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200